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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,710	09/29/2003	Robert G. Turcott	A03P3004-US1	4592

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EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,710	TURCOTT, ROBERT G.	
	Examiner	Art Unit	
	George Manuel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8 and 10-30* is/are pending in the application.

4a) Of the above claim(s) *24-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 12-23* is/are rejected.

7)☒ Claim(s) *10 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 5/3/07have been fully considered but they are not persuasive. Salo et al. do disclose and suggest determining an intracardiac impedance between electrodes 14 and 16 and determining a modified cardiac cycle parameter which is shorter than the intrinsic A-V interval sensed and determined in step 40 and comprises estimating optimal control parameters for maximizing cardiac performance based on an A-V interval which comprises a difference between the values representative of transient cardiac performance during each consecutive pair of evaluation periods using reference control parameters and test control parameters. In addition, step 44 suggests a selected modified cardiac cycle parameter comprises an estimated optimal control parameter.

Dawson et al do disclose and suggest alternating, from one evaluation period to another comprising the feedback loop from step, (204, 206) to step 200, between different sets of selected test control parameters, step (204 or 206) and a set of reference control parameters PDI, feedback between steps (204, 206) and 200, and detecting values representative of transient cardiac performances, step 208. Steps 202-204 are performed several times in a row using the same A-V delay and pacing rate for a period covering a respiration cycle of about 3 seconds.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4–8 and 12–23 are rejected under 35 U.S.C. 102(b) as being anticipated by Salo et al., U.S. Patent 5,487,752.

Regarding claims 1, 4, 5, 12, 13 and 21, Salo et al. disclose controlling an implantable device to deliver therapy to the heart of a patient while switching among sets of control parameters during a series of consecutive evaluation periods that are substantially equal in duration to one another and less than about 12 seconds each in duration (e.g., Figs. 2–3 and 5; column 3, lines 51–54 where 5 beats is approximately 5 seconds and it is the Examiner's position that the switching among sets of control parameters is the different intervals shown in blocks 40 and 44 of Fig. 5); controlling an implantable device to deliver therapy to the heart of the patient by alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters (e.g., Figs. 3 and 5, blocks 42, 44, 46 and 48); detecting values representative of transient cardiac performance corresponding to the different sets of control parameters during the evaluation period (e.g., Fig. 5, block 42), and estimating optimal control parameters for maximizing cardiac performance based on the values representative of transient cardiac performance (claim 1) (e.g., Fig. 5; column 4, lines 55–62).

With respect to claim 2, Salo et al. disclose evaluation periods are sufficiently short so that hemodynamic feedback systems of a patient do not have time to readjust the cardiovascular system of the patient to a substantially equilibrium state before the control parameters are switched again (e.g., column 4, lines 9–13).

Regarding claims 6–8, Salo et al. disclose measuring values representative of transient cardiac performance of the heart of the patient during each evaluation period, and determining the difference in transient cardiac performance based on a comparison of the measured values (claim 6) (e.g., Figs. 3 and 5; column 8, lines 10–13); periods of time over which the values representative of transient cardiac performance are measured are each set equal to substantially identical portions of a respiratory cycle (claim 7) and to about 4 seconds (claim 8), wherein each respiratory cycle comprises one inspiration and one expiration (claim 7) (e.g., Figs. 3 and 6; column 3, lines 38–40; column 6, lines 8–13).

With respect to claims 14–16, Salo et al. disclose the step of determining the difference in transient cardiac performance based on a comparison of the measured values includes the steps of: detecting a value representative of transient cardiac performance during an immediately preceding evaluation period, detecting a value representative of transient cardiac performance during the given evaluation period, and generating a difference value representative of a change in transient cardiac performance between the prior evaluation period and the given evaluation period such that a single difference value is generated for each evaluation period (claim 14) (e.g., Figs. 3 and 5); the step of estimating an optimal set of control parameters includes the steps of: associating each difference value with a set of control parameters employed during a corresponding evaluation period, fitting a single/separate curve to the difference values versus associated test parameter values/a set of parameter values; and identifying a set of preferred control parameters providing maximal difference

values as indicated by a single/separate curve and averaging a separate sets of preferred control parameters together to yield a single set of control parameters (claims 15–16) (e.g., Figs. 3, 5 and 6).

Regarding claims 17–20, 22 and 23, Salo et al. disclose adaptively adjust control parameters based on resulting changes in cardiac performance (e.g., column 8, lines 14–15, 27–28 and 40–42); and identifying control parameters that result in the most positive difference in cardiac performance as compared to all other control parameter values (claim 17) (e.g., Figs. 5 and 3); control parameters include one or more of: atrioventricular (AV) (claim 18) (e.g., Figs. 2, 3 and 6; column 4, line 62); values representative of one or more of stroke volume, cardiac output (claim 19) (e.g., Fig. 4, element 34, cardiac output sensor; column 4, lines 44–48 and 54–56); the initial step of determining whether to initiate an optimization procedure based on a change in one or more of heart rate (claim 20) (e.g., Figs. 1–4); an external programming device (claim 22) (e.g., column 2, line 35); all steps of the method are performed by an implantable device(claim 23) (e.g., Fig. 1; column 2, lines 36–37).

Claims 1, 4, 5–8, and 12–23 and are rejected under 35 U.S.C. 102(b) as being anticipated by Dawson et al., U.S. Patent 5,643,327.

Regarding claims 1, 4, 5, 12, 13, 21 and 23, Dawson et al. disclose controlling an implantable device (Fig. 1, element 10, pacemaker) to deliver therapy to the heart of a patient while switching among sets of control parameters during a series of consecutive evaluation periods that are substantially equal in duration to one another and less than about 12 seconds each in duration (e.g., Figs. 7A–7B; column 6, lines 51–53 and 63–65); detecting values representative of transient cardiac performance corresponding to

the different sets of control parameters during the evaluation period (e.g., Figs. 5, 5A–5B, 6, 7A–7B; column 5, lines 43–44 and 65–66; column 6, lines 1–3 and 13–14), and estimating optimal control parameters for maximizing cardiac performance based on the values representative of transient cardiac performance (e.g., Figs. 7A–7B; column 2, lines 59–66).

With respect to claims 6–8, Dawson et al. disclose measuring values representative of transient cardiac performance of the heart of the patient during each evaluation period, and determining the difference in transient cardiac performance based on a comparison of the measured values (claim 6) (e.g., Figs. 5, 5A–5B, 6, 7A–7B and 8; column 6, lines 51–59).

Regarding claims 14–16, Dawson et al. disclose the step of determining the difference in transient cardiac performance based on a comparison of the measured values includes the steps of: detecting a value representative of transient cardiac performance during an immediately preceding evaluation period, detecting a value representative of transient cardiac performance during the given evaluation period, and generating a difference value representative of a change in transient cardiac performance between the prior evaluation period and the given evaluation period such that a single difference value is generated for each evaluation period (claim 14) (e.g., Figs. 5, 5A–5B, 6, 7A–7B and 8; column 6, lines 51–63); the step of estimating an optimal set of control parameters includes the steps of: associating each difference value with a set of control parameters employed during a corresponding evaluation period, fitting a single/separate curve to the difference values versus associated test

parameter values/a set of parameter values; and identifying a set of preferred control parameters providing maximal difference values as indicated by a single/separate curve and averaging a separate sets of preferred control parameters together to yield a single set of control parameters (claims 15–16) (e.g., Figs. 5, 5A–5B, 6, 7A–7B and 8; column 6, lines 51–63).

Regarding claims 17–20, and 22, Dawson et al. disclose adaptively adjust control parameters based on resulting changes in cardiac performance (e.g., Figs. 5, 5A–5B; column 5, lines 43–55); and identifying control parameters that result in the most positive difference in cardiac performance as compared to all other control parameter values (claim 17) (Figs. 5, 5A–5B, 6, 7A–7B and 8; column 2, lines 59–66; column 6, lines 25–32); control parameters include one or more of: atrioventricular (AV) (claim 18) (Figs. 7A–7B and 9; column 2, lines 62–63); values representative of one or more of stroke volume, cardiac output (claim 19) (column 2, lines 60–61); the initial step of determining whether to initiate an optimization procedure based on a change in one or more of heart rate (claim 20) (column 2, line 61); an external programming device (claim 22) (column 4, line 26).

Allowable Subject Matter

Claims 10–11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to George Manuel whose telephone number is 571-272-4952. The Examiner can normally be reached on Monday - Friday, between 8:30 a.m. - 5:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner
Art Unit: 3762